DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-201/S-023
NDA 20-142/S-006
NDA 20-254/S-002

Novartis Pharmaceuticals
Attention: Adrian Birch
Executive Director
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Dear Dr. Birch:

Please refer to your supplemental new drug applications dated June 4, 1996, received June 10, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Voltaren (diclofenac sodium) enteric-coated Tablets (NDA 19-201);
Cataflam (diclofenac potassium) Tablets (NDA 20-142); and
Voltaren-XR (diclofenac sodium) Tablets (NDA 20-254)

We acknowledge receipt of your submissions dated July 8, 1996 (NDA 20-142 and 20-254) and January 21, 1998 (NDAs 19-201, 20-142 and 20-254).

These supplemental new drug applications provide for revisions to the package insert in accordance with Divisional class labeling issued on December 20, 1996.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 21, 1998).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-201/S-023, 20-142/S-006, 20-254/S-002." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Carmen DeBellas, Chief Project Management Staff, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonca Bull

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